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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,355	07/06/2001	H. Craig Dees	PHO-122	5998

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EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 07/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,355

Applicant(s)

DEES ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 12-18 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 1, 3-8, 19, 21-26, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Goers et al. Claims 1-11, 19-27, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bottiroli et al. Claims 1, 3-6, 19, 21-24, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultz et al. Claims 2 and 20 are rejected under 35 U.S.C. 103(a) as being obvious over Goers et al. for the reasons of record set forth in the Official Action mailed 7-07-2003.

Applicant's arguments filed 5-12-2003 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the cited references all require the presence of conjugate agents for the therapeutic efficacy of the disclosed halogenated-xanthene compounds. Applicants argue that the instant claims do not require conjugation with a targeting moiety and thus cannot be anticipated by or rendered obvious over Goers et al., Bottiroli et al., or Schultz et al.

First, it is noted that the instant claims are directed towards a medicament comprising at least one halogenated xanthene as a primary active component. The claims do not require that the halogenated xanthene comprise the sole active component within the entire medicament. The medicament is recited to "comprise" at least one halogenated xanthene, therefore other agents, such as conjugate agents, may be present within the medicament, potentially as a "secondary" active agent in contrast to the halogenated xanthene functioning as the primary therapeutic agent.

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There is no provision in the claims that requires that a conjugate group not be present in the claimed medicaments.

In regards to Goers et al., the teachings of Goers et al. clearly state that the photosensitizers, including in particular Rose Bengal (col. 20, lines 50-55), are disclosed as being therapeutic agents (i.e. photosensitizers including Rose Bengal) independent of the antibody attachment. (see col. 21, lines 9-13). Moreover, Goers et al. teach that the antibody or antibody fragment of the antibody therapeutic agent conjugate functions to deliver the conjugate to the target site, i.e. the antibody merely functions as a *targeting moiety* (see col. 28, lines 5-17), and not as the therapeutic agent. The photosensitizer is activated by a light source and its cytotoxic effect is mediated through the production of singlet oxygen, which results in toxicity to neighboring cells (col. 28, lines 45-68), this effect is not as a result of targeting moiety attachment.

Bottiroli et al. teach that the fluorogenic substrates can be administered for the treatment of tumors, i.e. as a medicament or pharmaceutical composition, comprising a dose varying from 1-to 10 mg/kg b.w. (i.e. halogenated xanthene is present in a concentration greater than about 0.0001% to less than about 20%), and administration can be systemic in the form of an isotonic saline solution, or as a suspension liposomes. The intracavitary route can administer the same preparation. Topical application requires the use of a water solution with the addition of substances favoring the absorption and penetration of the active principle (page 11, lines 1-14).

Schultz et al. disclose compositions comprising as a primary active functionality, a wide variety of fluoresces that may be employed either by themselves or in conjunction with quencher

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molecules as active functionalities. In one particular embodiment, the fluorescers include xanthene (col. 9, line 66), and more specifically may include Rose Bengal (col. 10, line 26).

Applicant's arguments are not persuasive, the instant claims remain rejected for the reasons of record.

Conclusion

3. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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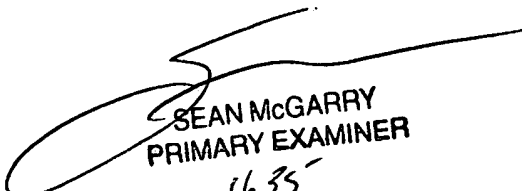
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Fri, 8:30AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
July 15, 2003


SEAN MCGARRY
PRIMARY EXAMINER
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